

## **REMARKS**

Claim 10, as herein amended, claims 13-15, as previously presented, and claims 11, 12, 18-20 and 23 as filed are pending in the application. Claims 1-9, 16, 17, 21, 22, 24, 26 and 28-36 are withdrawn as being directed to a non-elected invention. Claims 25 and 27 are cancelled herein without prejudice or disclaimer.

Applicant acknowledges with gratitude withdrawal of all previously-asserted grounds of rejection. The rejections asserted in the Office Action have been overcome by amendment or traversed by argument. No new matter is introduced by the amendments submitted herewith, which are fully supported by the specification as filed.

**1. The claims as amended are not anticipated by the cited prior art.**

Claims 10-15, 18-20, 23, 25 and 27 stand rejected as being anticipated under 35 U.S.C. §102(a) over the teachings of the Hasselmann reference. The Hasselmann reference is cited as teaching that extracellular tyrosine mRNA within apoptotic bodies from peripheral blood from melanoma patients. The reference is also cited by the Office as disclosing that “tumor-derived mRNA associated with apoptotic bodies remain stable in serum . . .”

Applicant respectfully contends that the Hasselmann reference is limited to a demonstration that apoptotic bodies can be detected in supernatant from a malignant melanoma cell line; indeed, the reference does not teach that apoptotic bodies can be detected in peripheral blood, contrary to the assertions in the Office Action, and Applicant respectfully contends that supernatant media would not be considered a “bodily fluid” by the skilled worker. Specifically, Hasselmann asserts “that tumor-derived mRNA associated with apoptotic bodies remains stable in serum.” (page 1489, left column), and posits “the possibility that apoptotic tumor cells are a source for plasma RNA....” (page 1489, last sentence). These quotations from the reference illustrate another limitation of the teachings of the Hasselmann reference: they are limited to tumor cells, and particularly to tumor cells *in vitro* after specifically and experimentally inducing apoptosis in the cells. The reference contains no teaching that apoptotic bodies from non-tumor cells are a source for plasma RNA. Moreover, the reference does not teach that mRNA in apoptotic bodies were detected in a bodily fluid. In addition, the reference does not teach that mRNA in apoptotic bodies were detected in a bodily fluid from a human without cancer. Applicant respectfully contends that these deficiencies

preclude assertion of the Hasselmann reference for anticipation of the pending claims as herein amended, wherein the bodily fluid is recited as being obtained “from a human without cancer.” Applicant respectfully requests that these amendments and argument overcome in part and traverse in part all grounds of rejection under 35 U.S.C. §102(a), and respectfully request that this ground of rejection be withdrawn.

**2. The claims as amended are non-obvious over the cited prior art.**

Claim 20 stands rejected as being obvious under 35 U.S.C. §103 over the teachings of the Hasselmann reference combined with the teachings of Mok. The teachings of the Hasselmann reference (including the deficiencies thereof) are asserted as discussed above. Applicant respectfully contends that the Action acknowledges the insufficiency of the Hasselmann reference alone to assert a *prima facie* case of obviousness against pending claim 20. Applicant further respectfully contends that the teachings of the Mok reference do not cure the deficiencies of the Hasselmann reference. Mok teaches detection of cellular RNA (isolated from ovarian cancer cells in culture) using microarray technology, and detection of marker proteins (prostatin) from blood plasma or serum using antibody binding technology (see Abstract). Neither of these teachings is directed to detecting RNA from blood plasma or serum or could be combined with the teachings of Hasselmann reference to achieve Applicant’s claimed invention.

Applicant thus respectfully contends that the asserted rejection under 35 U.S.C. §103 has been overcome by amendment and traversed by argument, and requests that the Examiner withdraw this ground of rejection.

**CONCLUSIONS**

Applicant believes that all pending claims are in condition for allowance, and respectfully request that the pending claims be passed to issue.

If Examiner Natarajan believes it to be helpful, she is invited to contact the undersigned representative by telephone at (312) 913-0001.

Respectfully submitted,  
**McDonnell Boehnen Hulbert & Berghoff LLP**

Dated: November 19, 2008

By: /Kevin E. Noonan/  
Kevin Noonan, Ph.D.  
Reg. No. 35,303